

REMARKS

Favorable consideration and allowance are respectfully requested for claims 1-5 in view of the foregoing amendments and the following remarks.

The rejection of claims 1 – 5 under 35 U.S.C. § 112, first paragraph, as lacking enablement for the *prevention* of subsequent stroke is respectfully traversed. Claim 1 has been amended to delete the reference to preventing stroke. The recent Office Action, at page 2, indicates that the specification is enabling for inhibiting a subsequent stroke. As amended the claims are directed to inhibiting a subsequent stroke and are properly enabled. Reconsideration and withdrawal of this rejection are therefore respectfully requested.

The rejection of claims 1 – 4 under 35 U.S.C. § 102(b) over Montgomery (WO 99/20260 A2) is respectfully traversed.

Montgomery indicate their invention would be useful in: (i) treating wasting disease; (ii) promoting trainability and fitness; and (iii) altering body composition and/or morphology, *see* the paragraph bridging pages 10 and 11. The reference describes wasting disease as generalized weight loss through a metabolic mechanism, *see* page 11, lines 15-16. Promoting trainability and fitness is described as improving exercise endurance, *see* page 12, line 21-22.

In example 2, Montgomery describe the treatment of military recruits with the AT1 antagonist Losartan (WO 99/20260, page 24). In particular, the reference teaches that an improved physical performance, as shown by a higher overall workload, was achieved after the treatment with Losartan. This was believed to be a result of an increased VO2max (the maximum rate of oxygen uptake and utilization). Military recruits are generally young and physically fit people who have previously not suffered from a stroke. As explained below, this is different from the presently-claimed invention.

The remaining examples address are also not directly relevant to the presently claimed invention: example 1 relates to ACE inhibitors in ischaemia; examples 3 and 4 relate to AT II plasma levels and cachexia; and example 5 relates to the ACE inhibitor enalapril and cardiac cachexia. Thus, the reference appears to be primarily directed to treating wasting disease and improving physical performance.

The instances where the reference discusses stroke are directed to primary stroke (the first instance of stroke suffered by a patient) and its recurrence, see the abstract and page 8. Thus, the reference's teaches are directed to therapies relating to an independent stroke. This means a stroke resulting from a cause other than the conditions existing following a prior stroke. In this sense, such a stroke is an *independent* stroke as the etiology is independent of any prior stroke.

In contrast, the presently claimed invention relates to inhibiting a subsequent stroke. As used in the claim, the term "subsequent stroke" refers to a stroke that occurs after a primary stroke and that is a *consequence* of the condition the patient is in as a result of the earlier stroke. Thus, to arrive at this invention, one must first realize that pathology of patients who have already suffered from a stroke is different from those who have not. The clinical condition of patients who have already suffered from one stroke is generally regarded as critical. Subsequent strokes are those strokes which are dependent from and a result of the conditions caused by the earlier stroke event.

Montgomery provides no indication that an AT₁-receptor antagonist might be useful in inhibiting such a subsequent stroke which follows is results from conditions associated with an earlier stroke. Montgomery is primarily directed toward applications that might be used on healthy, physically fit people, so as to increase their aerobic capacity. Thus, Montgomery concentrates on applications for healthy individuals. Montgomery does not discuss strokes in patients which have already suffered from a primary stroke and which are a result of that earlier stroke. Accordingly, reviewing the reference, one of skill in the art would

have no reason to select critically ill patients of the type who have already suffered a stroke and then try to inhibit further stroke events which result from the conditions caused by the earlier stroke.

Because of differences in the etiologies of these types of strokes, a treatment to avoid an independent stroke is not necessarily appropriate for treating a subsequent stroke which is, by definition, a result of conditions following an earlier stroke. As a result of these differences in the therapy of Montgomery when compared with the stroke inhibition method of the present claims, the anticipation rejection cannot be properly maintained. In particular, the Montgomery reference fails to teach the a method of inhibiting a subsequent stroke in a patient, as is presently claimed.

In view of the foregoing, reconsideration and withdrawal of this rejection are respectfully requested.

The rejection of claim 5 under 35 U.S.C. § 103(a) over Montgomery (WO 99/20260 A2) and further in view of Venkatesh *et al.* (6,517,871 B1) is respectfully traversed.

Venkatesh *et al.* is offered as teaching eprosartan mesylate as a known salt of eprosartan. This reference does not, however, make up for the failure of Montgomery to teach or suggest inhibiting a subsequent stroke as is presently claimed.

A proper obviousness rejection requires a teaching or suggest of every claim limitation. Because the cited combination of references fails to teach or suggest each and every claim limitation, reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

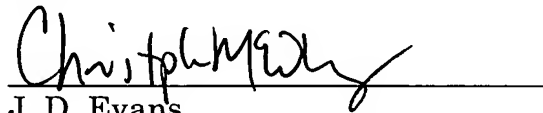
In view of the foregoing, the application is respectfully submitted to be in condition for allowance, and prompt favorable action thereon is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

Although a petition for an Extension of Time is submitted herewith, if necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #029300.52512US).

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Respectfully submitted,



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